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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,620	11/28/2000	Ronald Taylor	9426-048	8436

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PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/30/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/724,620

Applicant(s)
Taylor et al

Examiner
Karen Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-71 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24, 26-28, and 46-71 is/are allowed.
- 6) ☒ Claim(s) 23, 25, and 29-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7 6) ☐ Other:

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Response to Amendment

1. Claims 26-29, 32, 33, 35-39, 43-49^{6 KAC 7/23/02} have been amended. Claims 47-71 have been added.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The rejection of claims 23-46 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating or preventing cancer in an animal comprising administering an effective amount of anti-C3b(I) antibody, does not reasonably provide enablement for a method of treating or preventing cancer in an animal comprising administering an effective amount of multi-anti-C3b(I) antibodies, or an anti-C3b(I) antibodies which are immunospecific for C3b(I) linked to IgM or IgG bound to cancer cells, or anti-C3b(I) antibodies which are immunospecific for C3b(I) linked to proteins or lipids on cancer cells is withdrawn in light of applicants arguments.
4. The rejection of claims 23, 35- 37, 40-42, 44, 45 and 46 under 35 U.S.C. 103(a) as being unpatentable over Irie (Proceedings of the AACR, 1975, Vol. 16, p. 170) and Michael et al (FASEB, 1993, Vol. 7, p. A375 and Howard and Hughes-Jones (Complement-Mediated Lysis with Monoclonal Antibodies, In: Monoclonal Antibody Therapy, 1988, Vol. 45, pp. 3) and Neri

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et al (European Journal of Gynaecological Oncology, 1983, Vol. 4, pp. 37-40) in view of Perlmann et al (Journal of Experimental Medicine, 1981, Vol. 153, pp. 1592-1603) is maintained for reasons of record.

5. Claim 25, 29, 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Irie (Proceedings of the AACR, 1975, Vol. 16, p. 170) and Michael et al (FASEB, 1993, Vol. 7, p. A375 and Howard and Hughes-Jones (Complement-Mediated Lysis with Monoclonal Antibodies, In: Monoclonal Antibody Therapy, 1988, Vol. 45, pp. 3) and Neri et al (European Journal of Gynaecological Oncology, 1983, Vol. 4, pp. 37-40) and Perlmann et al (Journal of Experimental Medicine, 1981, Vol. 153, pp. 1592-1603) as applied to claims 23, 35- 37, 40-42, 44, 45 and 46 above, and further in view of Deo et al (Journal of Immunology, 1998 Feb 15, Vol. 160, pp. 1677-1686) is maintained for reasons of record.

6. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Irie (Proceedings of the AACR, 1975, Vol. 16, p. 170) and Michael et al (FASEB, 1993, Vol. 7, p. A375 and Howard and Hughes-Jones (Complement-Mediated Lysis with Monoclonal Antibodies, In: Monoclonal Antibody Therapy, 1988, Vol. 45, pp. 3) and Neri et al (European Journal of Gynaecological Oncology, 1983, Vol. 4, pp. 37-40) and Perlmann et al (Journal of Experimental Medicine, 1981, Vol. 153, pp. 1592-1603) and Deo et al (Journal of Immunology, 1998 Feb 15,

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Vol. 160, pp. 1677-1686) as applied to claims 25, 29, 30 and 32 above, and further in view of Paul (Immunology,) is maintained for reasons of record.

7. Claims 33, 34, 39 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Irie (Proceedings of the AACR, 1975, Vol. 16, p. 170) and Michael et al (FASEB, 1993, Vol. 7, p. A375 and Howard and Hughes-Jones (Complement-Mediated Lysis with Monoclonal Antibodies, In: Monoclonal Antibody Therapy, 1988, Vol. 45, pp. 3) and Neri et al (European Journal of Gynaecological Oncology, 1983, Vol. 4, pp. 37-40) and Perlmann et al (Journal of Experimental Medicine, 1981, Vol. 153, pp. 1592-1603) as applied to claims 23, 35- 37, 40-42, 44, 45 and 46 above, and further in view of Schlom (Monoclonal Antibodies, In: Molecular Foundations of Oncology, 1991, pp. 95-134) is maintained for reasons of record. .

8. Claims 24, 26 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Irie (Proceedings of the AACR, 1975, Vol. 16, p. 170) and Michael et al (FASEB, 1993, Vol. 7, p. A375 and Howard and Hughes-Jones (Complement-Mediated Lysis with Monoclonal Antibodies, In: Monoclonal Antibody Therapy, 1988, Vol. 45, pp. 3) and Neri et al (European Journal of Gynaecological Oncology, 1983, Vol. 4, pp. 37-40) and Perlmann et al (Journal of Experimental Medicine, 1981, Vol. 153, pp. 1592-1603) and Deo et al (Journal of Immunology, 1998 Feb 15, Vol. 160, pp. 1677-1686) in view of Carson et al (US 5,985,847) is maintained for reasons of record.

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9. Applicant argues that none of the cited references teaches methods of preventing or treating cancer in a animal comprising administering an anti-C3b(i) antibody. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Neri et al teach an immunoassay for circulating C3b(i) and correlates the level of C3b(i) in blood with the presence of a malignancy, thus Neri et al teach an antibody which binds to C3b(i). Howard and Hughes-Jones teach C3b(i) as the most important opsonin present on a target surface, and that the extent of phagocytosis of a target cell coated with C3b(i) is greatly enhanced by IgG also attached to the surface of said cell. Thus Irie and Michael et al and Howard and Hughes-Jones and Neri et al teach C3b(i) as a tumor antigen and antibodies which bind to C3b(i). Neither Irie nor Michael et al nor Neri et al teach a method of treating or preventing cancer by the administration of a anti-C3b(i) antibody. Perlmann et al teaches that target cells having C3b(i) were lysed by lymphocytes only in the presence of antibody, and C3b(i) enhanced ADCC more strongly than other complement fragments such as C3b or C3d. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to treat cancer by administering an anti-C3b(i) antibody immunospecific for C3b(i) on cancer cells to stimulate antibody dependent cytotoxicity in addition to administering IgG, IgM and complement components to enhance opsonization of said

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cancer cells. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Irie on the complement fixation of cancer cells associated with the presence of IgM and IgG, and the teachings of Michael et al and Neri et al on C3b(i) as a tumor marker and the teachings of Perlmann et al on the enhancement of ADCC by C3b(i).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may

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be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

July 29, 2002


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600